

Remarks:

A. Status of the Claims

Claims 1-33 were pending at the time the Restriction Requirement dated May 6, 2005, was mailed to Applicants. No amendments have been made to the claims, and no new claims have been added. Claims 1-33 are therefore currently pending.

B. Applicants Elect Group I

The Restriction Requirement requests restriction between one of the following two groups:

Group I, as exemplified by claims 1-20, drawn to compounds of formula (I) and compositions thereof;

Group II, as exemplified by claims 21-33, drawn to various methods of use.

In response to the Restriction Requirement, Applicants elect the Group I claims for further prosecution.

C. Further Elections Required by the Examiner

The Restriction Requirement requests the following additional election for further prosecution in this case:

In an election of Groups I-II, an election of a single compound (or set of compounds) is further required including an exact definition of each substitution on the base molecule (Formula I), wherein a single member at each substituent group or moiety is selected...In the instant case, Applicant must elect one representative for each of R1-R3, A, B, D, E, and v in formula I, and the point of attachment of each elected substituent must be specified.

The Restriction Requirement at page 3.

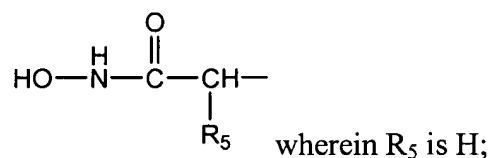
In response, Applicants elect the following for R₁, R₂, R₃, A, B, D, E, and v with traverse:¹

R₁ is H;

R₂ is H;

R₃ is H;

A is



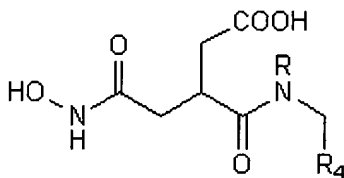
B is Absent;

D is -COOH;

E is H; and

v is 0.

With these substituents, formula (I) includes the following structure:



Applicants note that the Restriction Requirement does not indicate that Applicants must elect a specific substituent for the R or R₄ groups in formula (I). Applicants believe that the Restriction Requirement is correct in this regard; it is unnecessary to elect a specific substituent

¹ Applicants' arguments against the Restriction Requirement are based on the: (1) impropriety of requiring a restriction for the claimed Markush Groups and (2) lack of an additional burden—much less a “serious burden”—to search the full scope of R, R₁, R₂, R₃, A, B, D, E, and v together. Such arguments do not create an estoppel against Applicants and are not an admission that the restricted Groups are either patentably distinct or patentably indistinct from one another. This applies to all of Applicants' arguments against all of the Restrictions.

for the R and R₄ groups. For instance, the search and examination of the above Formula (I) (regardless of whether specific R and R₄ substituents are identified) can be made without presenting any additional burden on the Examiner, much less a “serious burden.” *See* MPEP § 803 (“If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.”). Formula (I) is sufficiently defined to search the art without having to elect a specific R and R₄ substituent. Therefore no election for R or R₄ has been made at this time.

D. Applicants Traverse the Restriction Requirement

Applicants traverse the Restriction Requirement for two reasons. First, it is inappropriate to require restriction of the claimed Markush Group. Restriction of a Markush Group is improper where the compounds within the group:

- (1) share a common utility; and
- (2) share a substantial structural feature disclosed as being essential to that utility.

See MPEP § 803.02. The claimed compounds share a common utility (non-limiting example as inhibitors of PHEX). Additionally, the claimed compounds share a “substantial structural feature.” For instance, the claimed compounds include a side chain bearing an ionizable acidic group which can allow the compounds to have activity as PHEX inhibitors (in non-limiting aspects). *See*, Applicants’ specification at page 5, line 28, to page 6, line 2. Therefore, restriction of Applicants’ claimed Markush Groups is improper.

Additionally, there is no “serious burden” to search all of the compounds in the claimed Markush Group. Stated another way, no further prior art searching is required for each compound listed in the Markush Groups because the claimed compounds include a side chain bearing an ionizable acidic group. As such, restriction of the claimed Markush Groups is

improper. MPEP § 803.02 (noting that “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.”).

Finally, it is improper and unreasonable to require restriction to “a single substituent” for each of the R₁, R₂, R₃, A, B, D, E, and v groups. For example, with respect to variable A Applicants have elected:

$$\text{HO}-\text{N}(\text{H})-\overset{\text{O}}{\parallel}{\text{C}}-\underset{\text{R}_5}{\text{CH}}-$$
 wherein R₅ is H. There is no “serious burden” to search Applicants’ elected A group wherein R₅ is H, a lower alkyl, or a substituted lower alkyl, for example. The elected A group is sufficiently defined to search the art regardless of the definition of R₅.

Additionally, the restriction to a specific substituent for R₁-R₃ is improper. There is no “serious burden” to search the claimed formula (I) where R₁-R₃ is H or a lower alkyl group, for example. Formula (I) is sufficiently defined to search the art regardless of whether R₁-R₃ is H or a lower alkyl group, for example.

The restriction to a specific substituent for B is improper. There is no “serious burden” to search the claimed formula (I) where B is a -CH₂ or absent, for example. Formula (I) is sufficiently defined to search the art regardless of whether B is CH₂ or absent, for example.

The restriction to a specific substituent for D is improper. There is no “serious burden” to search the claimed formula (I) where D is -COOH, -SO₂H, -SO₃H, -PO₃H₂; -OSO₃H or -OPO₃H₂. Formula (I) is sufficiently defined to search the art regardless of whether D is any one of the claimed groups.

The restriction to a specific substituent for E is improper. There is no “serious burden” to search the claimed formula (I) where E is H, -COOH, -CH₂COOH, -CH₂OH, -CH₂CH₂OH, or -CONH₂, for example. Formula (I) is sufficiently defined to search the art regardless of whether E is any one of these groups.

The restriction to a specific substituent for v is improper. There is no “serious burden” to search the claimed formula (I) where v is zero or one. Formula (I) is sufficiently defined to search the art regardless of whether v is zero or one.

Applicants therefore request that the restriction to “one representative for each of R₁-R₃, A, B, D, E, and v in formula (I), and the point of attachment of each elected substituent must be specified” is improper and should be withdrawn. Alternatively, Applicants have provided acceptable suggestions for each of R₁-R₃, R₅, A, B, D, E, and v in formula (I) in the above paragraphs.

E. Conclusion

Applicants believe that this is a full and complete response to the Restriction Requirement dated May 6, 2005. Applicants request that the Restriction Requirement to the specific compounds be withdrawn and that the elected claims be examined for the their full scope.

Petition for a Three-Month Extension of Time:

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for a three-month extension of time to and including September 6, 2005, in which to respond to the Restriction Requirement dated May 6, 2005. Pursuant to 37 C.F.R. § 1.17, a check in the amount of \$ 510.00 is enclosed, which is the process fee for a three-month extension of time for a small entity status. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/GOUD:045US.

Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-3020.

Respectfully submitted,



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